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What information on sham acupuncture is given to trial participants and how does it affect blinding and outcomes?



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Purpose: This study aimed to identify how and what information is given to participants of randomised sham-controlled trials (RCTs) of acupuncture, and how it may affect blinding and outcomes.

Methods: We invited authors of the RCTs published in PubMed from 1985 to November 2013 to send us participant information leaflets (PILs) used in their trials. Based on the degree of information disclosure, collected PILs were categorised by structured content analysis. Chi-square test, Mann-Whitney U test, or independent t-test were used to test differences in blinding and outcomes among different information disclosure categories. We used blinding index (BI) of acupuncture and sham groups for each trial and standardised mean difference (SMD) of primary outcomes in a random effects model.

Results: From content analysis of the collected 65 PILs, three categories were identified according to how much information is given about sham acupuncture; Full Disclosure (FD), Deceptive Disclosure (DD), and Missing Information (MI). Studies of non-Asian countries were more likely to provide detailed information on sham acupuncture in PILs than those from Asian countries ($p = 0.011$). Though not statistically significant, blinding analysis showed that sham acupuncture groups in the studies from DD & MI categories had a lower BI value reflecting more wishful thinking than those from FD category (BI -0.21 vs. -0.16). Outcome analysis revealed that studies in DD & MI categories significantly favoured acupuncture than those in FD category (SMD -0.43 vs. -0.12; $p = 0.03$), probably due to enhanced expectations.

Conclusion: Further research on adequate information disclosure and its potential impact on blinding and outcomes are urgently needed. Further in-depth studies utilising both qualitative and quantitative methods are warranted to better understand complicatedly intertwined factors in acupuncture trials.

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Exploring the scientific new model for Chinese medicine etiology research by using Cohort Study combined with Grounded Theory in sequence



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Purpose: Chinese medicine etiology theories are predominantly initiated by experts opinions and/or their clinical experiences, which are not be evaluated by scientific clinical trials, and it is a truly key issue to develop evidence-based Chinese medicine etiology research to achieve better outcomes by using Chinese medicine for patients. Based on our previous methodology researches in Chinese medicine and the observation on Chinese medicine curative effect evaluation according to “pathogeny from syndrome differentiation and treatment from pathogeny” principle.

Methods: This study proposes scientific hypotheses that the design of Cohort Study combined in sequence with Grounded Theory would help to establish a new methodology model for Chinese medicine etiology research. And Prospective Cohort Study will be used in this study to explore the interaction between Gastrointestinal Heat Retention Syndrome and Wind-warm Lung-heat Disease to identify their cause-effect relationship as a pioneering try in Chinese medicine to supplement the traditional etiology knowledge that deficiency of ZhengQi is an instinct factor to drive Wind-warm Lung-heat Disease. Then the qualitative method of Grounded Theory will be used to induce and generalize a theory by concerning and processing raw data from the perspectives of Chinese medicine practitioners’ understandings and experiences towards the interaction between Gastrointestinal Heat Retention Syndrome and Wind-warm Lung-heat Disease to theorize the results of Cohort Study.

Results: All these will help to appraise the stability and the effect of this etiology research model which is deemed to be scientific and specific for Chinese medicine to embody the principles of CM and characteristics of differentiation of syndromes with broadly feasibility.

Conclusion: The scientific new model for Chinese medicine etiology research can be built by using Cohort Study combined with Grounded Theory in sequence

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